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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,967	06/19/2000	Bertil Abrahamsson	1103326-0624	6706

7590 10/28/2003

White & Case
1155 Avenue of the Americas
New York, NY 10036-2787

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/28/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/581,967

Applicant(s)

ABRAHAMSSON ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29 and 33-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29, 33-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination under 1.114 and Preliminary Amendment dated 3/27/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

- a. The breadth of the claims;

The claims are drawn to a method for the prophylactic treatment of a subject. For this claim to be true the formulation would have to completely prevent every occurrence of hypercholesterolemia in every patient treated with the formulation.

- b. The nature of the invention;

The nature of the invention is that of a pharmaceutical composition comprising an IBAT inhibitor and a bile acid binder, where the IBAT inhibitor and the bile acid binder are

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released at different points along the intestinal tract. The claims also include methods treatment the formulation.

c. The state of the prior art;

The prior art establishes that hypercholesterolemia is a treatable disorder, but has yet to establish a preventative formulation that prevents all occurrences in all patients.

d. The level of one of ordinary skill;

Artisans of ordinary skill as shown in Hirakawa et al (USPN 5,614,220) and Brieady et al (USPN 5,723,458) have established that IBAT inhibitory agents can be useful in the treatment of hypercholesterolemia, yet a truly preventative compound that would eliminate the disorder all together.

e. The level of predictability in the art;

A skilled artisan would predict that the IBAT inhibitor agents disclosed in the prior art would be useful in the treatment of hypercholesterolemia and other associated disorders, but the total prevention of the disorder would not be an expected result. Such a result would have to be supported by data.

f. The amount of direction provided by the inventor;

The inventor provides direction for a treatment of the disorder but does not for the total prevention of the disorder in every possible patient.

g. The existence of working examples; and

The working examples provide teachings to the treatment of the disorder, and not to the complete prevention of hypercholesterolemia.

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h. The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

A skilled artisan would have to distribute a dosage of the claimed invention to every single sufferer of hypercholesterolemia and show that the disorder was prevented to a point where the disorder could not re-occur.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 29, 33 – 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. With regard to claims 29, 33 – 35, the claims recite the language: “wherein the bile acid binder is coating layered for targeted release”. It is unclear to the examiner whether the bile acid binder acts as a coating to the formulation or is incorporated into a separate coating composition. Whether applicant intends for the bile acid binder to be coated or act as a coating is a cause for confusion and renders the indefinite until clearer language can be established.

6. Claims 36 – 45 are rejected by extension as being dependent from indefinite claims.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600